

REMARKS/ARGUMENTS

The claims have been divided into Groups as follows:

Group I: Claims 1-30 drawn to compounds and compositions with a pyridyl-piperidinyl-pyridyl core where in formula 1 claim 1, 1 is 1; m is 0, X is NR₄, R₄ is phenyl, W1 = W2 = N, shown as structure I figure 1.

If this group is elected, a further election of a single disclosed species representing this group is also required.

Group II: Claims 1-4, 6-9, 11-14, 16-19, 21-24, 26-30 drawn to compounds and compositions with a phenyl-piperidinyl-pyridyl core where in formula 1 claim 1, 1 is 1, m is 0, X is NR₄, R₄ is phenyl, W1 = CH, W2 = N, shown as structure II figure 1.

If this group is elected, a further election of a single disclosed species representing this group is also required.

Group III: Claims 1-4, 6-9, 11-14, 16-19, 21-24, 26-30 drawn to compounds and compositions with a pyridyl-piperidinyl-phenyl core where in formula 1 claim 1, 1 is 1, m is 0, X is NR₄, R₄ is phenyl, W1 = N, W2 = CH, shown as structure III figure 1.

If this group is elected, a further election of a single disclosed species representing this group is also required.

Group IV: Claims 1-4, 6-9, 11-14, 16-19, 21-24, 26-30 drawn to compounds and compositions with a phenyl-piperidinyl-phenyl core where in formula 1 claim 1, 1 is 1, m is 0, X is NR₄, R₄ is phenyl, W1 = CH, W2 = CH, shown as structure IV figure 1.

If this group is elected, a further election of a single disclosed species representing this group is also required.

Group V: Claims 46-50, drawn to method of "inhibiting histone deacetylase" with one of the compound groups I-IV.

If this group is elected, a further election of a single disclosed species of I-IV useful in "inhibiting histone deacetylase", is also required.

Group VI: Claims 51-55, drawn to methods of treating cancer with one of the compound groups I-IV.

If this group is elected, a further election of a single disclosed "cancer" and a single disclosed species useful in treating the elected "cancer", is also required.

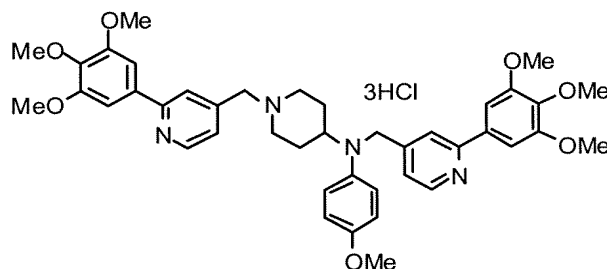
Group VII: Claims 57-60, drawn to methods of "facilitating gene therapy" with one of the compound groups I-IV.

If this group is elected, a further election of a single disclosed “gene therapy” and a single disclosed species useful in facilitating the elected “gene therapy”, is also required.

Applicants elect, with traverse, Group I, Claims 1-30, for examination.

As a single disclosed species, for examination purposes only, Applicants elect the compound of Example 10, page 48, in the specification:

4-[N-(4-methoxyphenyl)-N-[[2-(3,4,5-trimethoxyphenyl)pyridin-4-yl]methyl]amino]-1-[[2-(3,4,5-trimethoxyphenyl)pyridin-4-yl]methyl]piperidine trihydrochloride:



Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (MPEP §803). The burden is on the Examiner to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP §803). Moreover, when citing lack of unity of invention in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other group specifically describing special technical features in each group (MPEP § 1893.03(d)).

The Office has asserted that Groups I - VII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack a significant structural element qualifying as a special technical feature that defines a contribution over the prior art. The examiner has cited a search of the core structure and indicated a large number of hits on the “core.” However, there is no indication that the compounds of this invention are known.

Annex B of the Administrative Instructions under the PCT at (b) Technical Relationship states:

“The expression “special technical features” is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).”

Applicants respectfully submit that the Examiner has not provided any indication that the contents of the claims interpreted in light of the description was considered in making the assertion of a lack of unity and therefore has not met the burden necessary to support the assertion.

Moreover, MPEP § 1850 (B) “*Markush Practice*” states:

“When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all the alternatives;”

Applicants respectfully submit that in the above identified application, the compounds of formula (1) in Claim 1 do have the common property as defined in Claim 1 (histone deacetylase inhibitor) and therefore meet criterion (A).

Relative to criterion (B)(1) MPEP § 1850 (B) defines “significant structural element is shared by all the alternatives” as “cases where the compounds share a common chemical structure which occupies a large portion of their structures.” Moreover the PCT in the PCT International Search and Preliminary Examination Guidelines provide guidance in this matter through example analysis. Applicants respectfully submit that Examples 18 and 19 on pages 84 and 85 of the document are suitable references relative to analysis of formula (1).

Applicants submit that the compounds of formula (1) all share the common structure of an the structural backbone indicated in formula (1) and that this common structure occupies a sufficiently large portion of the structure to meet criterion (B)(1).

Because the compounds of formula (1) meet the criteria of (A) and (B)(1) above, Applicants submit that the claims of the above-identified application relate to a single general inventive concept under PCT Rule 13.1 and therefore unity of invention is not lacking.

Furthermore, 37 C.F.R. § 1.475(b) states in pertinent part:

“An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(2) A product and a process of use of said product; . . .”

In addition, The MPEP §806.03 states:

“Where the claims of an application define the same essential characteristics of a *single* disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.”

Applicants respectfully submit that the Office has not considered the relationship of the inventions of Groups I-VII with respect to 37 C.F.R. § 1.475(b)(2) and MPEP §806.03. Therefore the burden necessary according to MPEP § 1893.03(d) to sustain the conclusion that the groups lack of unity of invention has not been met. For this reason, Applicants submit that the Requirement for Restriction should be withdrawn.

Applicants respectfully traverse the Restriction Requirement on the grounds that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the identified groups.

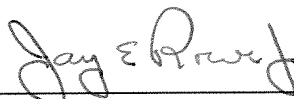
For the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the Restriction Requirement. Withdrawal of the Restriction Requirement is respectfully requested.

Application No. 10/510,759
Reply to the Restriction Requirement of July 13, 2007

Applicants submit that the above-identified application is now in condition for examination on the merits, and early notice of such action is earnestly solicited.

Respectfully submitted,

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